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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,522	12/01/2000	Hiroshi Nagai	1830/49264	8049

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EXAMINER

SCHNIZER, HOLLY G

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 03/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

FILE 06**Office Action Summary**

Application No.

09/647,522

Applicant(s)

NAGAI ET AL.

Examiner

Holly Schnizer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 17-36 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Status of the Claims

The Preliminary Amendment filed February 28, 2001 as Paper No. 5 has been entered. Claims 1-16 were cancelled. Claims 17-36 were added. Therefore, Claims 17-36 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 17-18, 22, 32, and 36, drawn to a polypeptide having hemolytic activity, classified in Class 530, subclass 350.

Group II, claim(s) 19-21, and 23-29, drawn to a nucleic acid molecule encoding the polypeptide having hemolytic activity, classified in Class 536, subclass 23.1

Group III, claim(s) 30-31, drawn to a process of isolating a protein from natural sources, classified in class 530, subclass 412.

Group IV, claim(s) 33, drawn to a method of stimulating platelet agglutination by administering a protein having hemolytic activity, classified in class 514, subclass 2.

Group V, claim(s) 34-35, drawn to an antibody specific for the polypeptide having hemolytic activity, classified in class 530, subclass 387.1.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

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The technical feature linking Groups I-V appears to be that they all relate to polypeptides with hemolytic activity.

However, Allison et al. (Infect. Immun. (July 1997) Vol. 65(7): pp. 2765-2771) teaches a hemolysin that has hemolytic activity (see abstract). (The examiner notes that Claim 1 is drawn to a polypeptide having hemolytic activity that may have any number of amino acid additions, deletions, or substitutions from the amino acid sequences claimed. Therefore, the claim is interpreted to encompass hemolytic proteins of any sequence.)

Therefore, the technical feature linking the inventions of Groups I-V does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

The special technical feature of Group I is considered to be a polypeptide having hemolytic activity.

The special technical feature of Group II is considered to be a nucleic acid encoding the polypeptide having hemolytic activity.

The special technical feature of Group III is considered to be a process of isolating a protein with hemolytic activity from natural sources.

The special technical feature of Group IV is considered to be a method of stimulating platelet agglutination by administering a protein with hemolytic activity.

The special technical feature of Group V is considered to be an antibody specific for a protein with hemolytic activity.

Accordingly Groups I-V are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Additional Restriction to a Single Polypeptide, polynucleotide, or Antibody

The claims of Groups I-V are drawn to a multitude of polypeptides (SEQ ID NOs: 1, 2, 3, or 5), polynucleotides encoding the polypeptides, antibodies thereto, and methods of using these compounds. The inventions of each of these polypeptide sequences listed above do not relate to a single inventive concept under PCT Rule 13.1

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because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The polypeptides of SEQ ID NOs: 1, 2, 3, and 5 have different structural features (sequences) and therefore functional features. And, there is no apparent shared common core structure and no apparent shared art recognized function. For example, the polypeptides of SEQ ID NOs: 1 (14 aa), 2 (16aa), 3 (15aa), and 5 (450aa) all have completely different amino acid sequences and lengths and therefore would be expected to have different functions.

Therefore, upon election of one of Groups I-V, Applicant is required additionally to elect a single polypeptide, polynucleotide (encoding a single polypeptide) or antibody (specific for a single polypeptide sequence) depending on the inventive Group which is elected and including the method groups. This requirement is not to be construed as a requirement for an election of species, since each of the compounds recited in alternative form is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (703) 305-3722. The examiner can normally be reached on Mon. & Thurs., 8am-5:30pm and Tues. & Wed. 9-2:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

HS
Holly Schnizer
March 21, 2002

Christopher S. F. Low
CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600